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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,549	07/16/2003	Marianne O'Shea	059490-5016	5947

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EXAMINER	
WILLIAMS, LEONARD M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/619,549	O'SHEA ET AL.	
	Examiner	Art Unit	
	Leonard M. Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☒ Claim(s) *15-23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/6/04 AND1/26/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Claim Objections

Claims 14-23 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend on another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-23 are rejected under 35 U.S.C. 1 12, first paragraph, because the specification, while being enabling for treating a common cold, does not reasonably provide enablement for preventing a common cold. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547

the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the ad; (4) the predictability or unpredictability of the ad; (5) the breadth of the claims', (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The Nature of the Invention:

The rejected claims are drawn to a method of preventing or treating a common cold in a mammal, or of treating or ameliorating the symptoms of a common cold in a mammal, which comprises administering one or more conjugated fatty acids and derivatives thereof.

(2) Breadth of the Claims:

The instant claims embrace preventing or treating a common cold in a mammal.

(3) Guidance of the Specification:

The guidance of the specification as to the prevention of chronic or acute rejection is completely lacking. The specification provides two examples on pages 9-11:

EXAMPLES 1 AND 2

In Vivo Study

Protocol

45 human volunteers suffering from the common cold were used in the study. 21 subjects were administered conjugated linoleic acid (CLA) and the other 24 subjects

were given a placebo.

The 21 subjects underwent pre-treatment with CLA at a level of 1.7 g/day for 4 weeks. 24 subjects underwent pre-treatment with placebo (HOSF; high oleic sunflower acids). All subjects were inoculated at day 0 by intranasal exposure to human Rhinovirus (HRV) and the two groups were monitored daily for the next 5 days. The effects of the two types of treatment were determined by using the Jackson Score (validated in severity of symptoms) and the effects of the symptoms on its own on day 0-5. Symptoms were assessed using a Jackson Score validated in severity from 0=absent to 3=very severe. The following symptoms were rated:

Runny nose Stuffiness Sneezing Sore throat Cough Headache Malaise Chilliness

EXAMPLE 1

Recovery After the Common Cold

The primary endpoint for the study was the frequency of clinical colds defined in accordance with the modified Jackson criteria. A subject will be considered to have a clinical cold if he/she has a cumulative symptom score of 6 or greater over the five days post-challenge (adjusted for any baseline symptom) and either reports runny nose on 3 post challenge days or responds "yes" to the question on day 5 post challenge whether he/she feels that he/she has had a cold during the previous 5 days.

FIG. 1 is a plot of Jackson Score against number of days for the patients treated with the placebo (upper line, black) and those treated with CLA (lower line, grey).

The results show that at day 2 already, the severity of the common cold is lower in the

CLA treated people. Given the fact that the difference already occurred at day 2 demonstrated the positive effect of CLA.

EXAMPLE 2

Treatment of Symptoms

Total symptoms of the individuals were checked in the morning (am) and in the afternoon (pm). The results of the test in the morning are shown in FIG. 2 and the results of the test in the afternoon are shown in FIG. 3; both plots are of Total Symptom Score against number of days. In FIGS. 2 and 3, results for the group of people treated with CLA are shown on the left in grey (Series 1) and for people given the placebo are shown on the right in dark grey (Series 2).

The results showed that the total symptom score at day 2 until the end of the study is lower in the CLA treated people. Neither experiment demonstrated prevention of a common cold.

(4) Working Examples:

Applicant does not provide any working examples for the prevention of a common cold.

(5) State/predictability of the Art:

The state of the art regarding treating a common cold is relatively high. However, the state of the art for prevention of a common cold is underdeveloped.

(6) The Quantity of Experimentation Necessary:

The instant claims read on the prevention of a common cold in all of its forms. As discussed above, the specification fails to provide sufficient support for completely protecting against a common cold. Applicant fails to provide information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Accordingly the claims are evaluated as a method for treating a common cold in a mammal and not as a method for preventing a common cold in a mammal.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-23 provides for the use of a conjugated fatty acid or a derivative thereof, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 12-23 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under

35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Cook et al. (US Patent No. 5827885).

Cook et al. teach, in col. 2 lines 30-50, a method of treating symptoms associated with the production of TNF production in animals, including humans, caused by viral infection via administration of a conjugated linoleic acid (CLA).

Cook et al. teach, in col. 8 lines 40-65, that the CLA compositions and their non-toxic derivatives can be added to an animal or human's food or formed into tablets, capsules, solutions, and emulsions. The exact amount to be administered depends on the CLA used but generally will be from about 1ppm to about 10,000ppm in an animal's or human's diet and that the CLA amounts to be added can range from 0.01% to 2.0% or more by weight of the animal's or human's food. As evidenced by the sample menu for a 2000 calorie food pattern from the USDA's website (mypyramid.gov/downloads/sample_menu.pdf) the total amount of food consumed daily

(including proteins, carbohydrates, total fats and total dietary fiber) is 460g. If the added CLA is to be 0.01-2% then it would correspond to 0.046-9.2g daily.

Cook et al. teach, in col. 9 lines 4-20, that the method comprising administration of CLA to an animal, including a human, for the treatment of symptoms associated with viral infection includes picornavirus (which includes rhinovirus), togavirus, paramyxoviris, orthomyxovirus, rhabdovirus, reovirus, retrovirus, bunyavirus, coronavirus, arenavirus, parovirus, papovavirus, adenovirus, herpesvirus, and poxvirus anticipating the "...method of...treating a common cold...which comprises administering...conjugated fatty acids and derivatives thereof" of claim 1, the "...method...wherein said mammal is human" of claim 2, the "...method...wherein said mammal is administered a composition comprising a conjugated fatty acid or a derivative thereof and wherein said composition is a pharmaceutical composition, a foodstuff or a food supplement" of claim 3, the "...method wherein the conjugated fatty acid or derivative thereof is conjugated linoleic acid or a derivative thereof" of claim 4, the "...method...for reducing the recovery time after a common cold" of claim 5, the "...method...wherein the common cold is caused by a coronavirus or a rhinovirus" of claim 6, the "...method...wherein the amount of conjugated fatty acid or derivative thereof is from 0.1 to about 20g of conjugated fatty acid or derivative thereof per day" of claim 7, the "...method...wherein the conjugated linoleic acid or derivative thereof comprises trans10, cis12, and cis9, trans11 isomers and the weight ratio of trans10, cis12 isomer to cis9, trans11 isomer is at least 1.2:1" of claim 8, the "...method...wherein said mammal is administered a composition comprising a conjugated fatty acid or a

derivative thereof wherein said composition is a foodstuff..." of claim 9, the "...method...wherein said mammal is administered a composition comprising a conjugated fatty acid or a derivative thereof and wherein said composition is a pharmaceutical composition..." of claim 10, the "...method...wherein said mammal is administered a composition...wherein said composition is a food supplement in the form of a soft gel or hard capsule..." of claim 11, the "...use of a conjugated fatty acid derivative thereof in the manufacture of a composition..." of claim 12, the "...use...wherein the mammal is human" of claim 13, and the "...use...wherein the composition is a pharmaceutical composition, a foodstuff or a food supplement" of claim 14.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LMW

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER